

PATHWAY
MEDICAL TECHNOLOGIES

MAR 11 2009

510(k) SUMMARY

General Information:

Date of Summary Preparation: February 6, 2009

Name and Address of Manufacturer: Pathway Medical Technologies, Inc.
10801 120th Ave NE
Kirkland, Washington 98033

Contact Person: Brit Baird
Regulatory Affairs Specialist
Phone: 425-636-4137
Fax: 425-636-4001

Trade Name: Jetstream G2TM System

Common Name: Peripheral Atherectomy Catheter

Regulation Number: 21 CFR 870.4875

Regulation Name: Intraluminal Artery Stripper

Regulatory Class: Class II

Classification Panel: Cardiovascular

Product Code: MCW

Predicate Devices: Manufacturer: Pathway Medical Technologies, Inc.
(1) JetstreamTM Pathway PVTM
Atharectomy System (K083489)
(2) Jetstream G2TM System (K083837)

Indications for Use: The Jetstream G2TM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥ 3.0 mm in diameter. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Device Description: The Jetstream G2™ System is an atherectomy catheter system designed with an expandable cutting tip for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to a collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The Jetstream G2™ System consists of two primary components: (1) a Catheter and Control Pod and (2) a Console, which are packaged separately. Each of these system components is described generally as follows:

- **Jetstream G2™ Catheter and Control Pod:** A sterile, single-use unit consisting of an electrically driven Catheter and Control Pod. The Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities. The Control Pod provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double-pouched tray.
- **PV Console:** A reusable compact Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

This 510(k) is for the incorporation of the identical design modifications recently cleared under 510(k) K083837 (for the Jetstream G2 System) into the predicate Jetstream System cleared under 510(k) K083489.

Substantial Equivalence: The Jetstream G2 System is substantially equivalent to the specified predicate devices. The device has the identical indications for use and the same technological characteristics. Bench testing was completed and provided to support the safety and effectiveness of the modifications that were the subject of this 510(k).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

Pathway Medical Technologies, Inc.
c/o Mr. Brit Baird
Regulatory Affairs Specialist
10801 120th Ave NE
Kirkland, WA 98033

Re: K090325
Jetstream G2 System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: February 6, 2009
Received: February 9, 2009

Dear Mr. Baird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

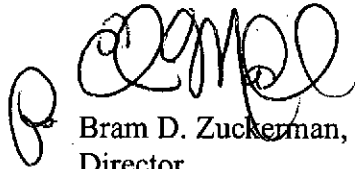
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the typed name.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K090325

Device Name: Jetstream G2™ System

Indications for Use: The Jetstream G2™ System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥ 3.0 mm in diameter. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dinner R. Volmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090325